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Applicant(s):	F. Barry Bays, et al.	
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APPEAL BRIEF UNDER 37 CFR § 41.37

This Appeal Brief is filed pursuant to the January 30, 2007 Notice of Appeal to the Board of Patent Appeals and Interferences.

1. *Real Party in Interest*

The real party in interest in this appeal is Wright Medical Technology, Inc., the assignee of the above-referenced patent application.

2. *Related Appeals and Interferences*

There are no related appeals or interferences involving this application or its claimed subject matter.

3. *Status of Claims*

Claims 23-44 are pending. Claims 1-22 are cancelled. No other claims are pending. All claims stand rejected as unpatentable over a combination of prior art references as set forth in greater detail below. The prior art rejection of all pending claims is appealed herein.

4. *Status of Amendments*

All amendments have been entered.

5. *Summary of Claimed Subject Matter*

The invention is an apparatus for preparing a bone graft composite comprising a bone graft material **M** and a bone marrow aspirate **A**. The invention allows the bone graft material **M** and the bone marrow aspirate **A** to be mixed (i.e. infused) in the operating room. (**Specification, p. 10, lines 2-4; page 14, lines 12-14**). In the embodiment of independent **Claim 23**, the apparatus comprises a tube **10** having a first open end **12** and a second open end **14**. (**Figure 2**; **Specification, p. 8, lines 16-19, p. 10, lines 6-7**). A first end cap **16** (also designated as end cap **44** in **Figure 3)** is removably coupled to the first open end **12**. (**Figure 3;** Specification, p. 11, lines 3-4). The first end cap **16** has a passage therethrough to allow fluid communication between a bone marrow aspirate delivery member **100** and the tube **10**. (**Figures 3 and 6B**). A trailing end **48** of the end cap **16** (designated end cap **44** in **Figure** 3) is configured for selective attachment to a bone marrow aspirate delivery member, such as a syringe **100**. (**Figures 1, 3, 6A, 6B; Specification, p. 11, line 31-p. 12, line 2**). A second end cap **18** is removably coupled to the second end **14**. (**Figure 2; Specification, p. 11, lines 3-4**). The second end cap **18** has a passage therethrough to allow fluid communication between the tube **10** and a filter **50**. (**Figures 2, 3, 4, 6B and 7; Specification, p. 12, line 28-p. 13, line 2**). A leading end **48** of the second end cap **18** is configured for selective attachment of a filter **50**. (**Figure 2; Specification, p. 11, lines 6-7; p. 11, line 31-p. 12, line 2**). A filter member **20** is removably coupled to the leading end **48** of the second end cap **18**. (**Figures 1 and 2; Specification, p. 11, lines 6-7 and p. 11, line 31-p. 12, line 2**). As shown in **Figure 4**, a filter **50** is in the filter member **20**. (**Figure 4**). The filter **50** is configured to prevent bone marrow aspirate **M** from passing therethrough while permitting air to pass therethrough. (**Figures 6B and 7; Specification, p. 11, lines 9-12, p. 12, lines 3-5, p. 13, lines 1-2**). The filter is in fluid communication with the tube **10** via the passage of the second end cap **18**. (**Figures 2, 3, 4, 6B and 7; Specification, p. 12, line 28-p. 13, line 2**). The tube **10** contains a bone graft material **M**. (**Figure 1; Specification, p. 10, lines 11-13**).

In dependent **claim 24**, which depends from **claim 23**, the bone graft material **M** is selected from the group consisting of calcium sulfate, calcium phosphate, tri-calcium phosphate, hydroxyapatite, coral hydroxyapatite, demineralized bone matrix, and mineralized bone matrix. (**Specification, p. 10, lines 14-21**). In dependent **claim 25**, which depends from independent **claim 23**, the bone graft material comprises tri-calcium phosphate. (**Specification, p. 10, lines 14-16**). Dependent **claim 26**, which depends from independent **claim 23**, specifies that the bone graft material **M** is porous to bone marrow aspirate. (**Figure 1; Specification, p. 10, lines 14-15 and 23-28**). Dependent **claim 27**, which depends from independent **claim 23**, specifies that the bone graft material comprises a plurality of small pieces of bone graft material. (**Figure 1; Specification, p. 10, lines 23-28**).

Dependent **claim 28**, which depends from independent **claim 23**, further comprises the first end cap **16** sealed by a removable first sealing cap **22** on a trailing end of the first end cap **16**. (**Figures 1-2; Specification, p. 11, lines 8-9**). Dependent **claim 29**, which depends from dependent **claim 28**, further comprises the filter member **20** sealed by a removable second sealing cap **24** on a leading end of the filter member **20**. (**Figures 1-2; Specification, p. 11, lines 8-9**).

Dependent **claim 30**, which depends from dependent **claim 23**, further comprises a first washer **38** disposed between the first end cap **16** and the first end **12** of the tube **10**. (**Figure 2; Specification, p. 11, lines 23-26**). Dependent **claim 31**, which depends from dependent **claim 30**, further comprises a second washer **40** disposed between the second end cap **18** and the second end **14** of the tube **10**. (**Figure 2; Specification, p. 11, lines 23-26**).

Dependent **claim 32**, which depends from dependent **claim 25**, further specifies that the bone graft material **M** comprises a plurality of small pieces of bone graft material **M**. (**Figure 1; Specification, p. 10, lines 23-28**). Dependent **claim 33**, which depends from dependent **claim 32**, further comprises a first washer **38** disposed between the first end cap **16** and the first end **12** of the tube **10**, and a second washer **40** disposed between the second end cap **18** and the second end **14** of the tube **10**. (**Figure 2; Specification, p. 11, lines 23-26**). Dependent **claim 34**, which depends from dependent **claim 33**, further comprises the first end cap **16** sealed by a removable first sealing cap **22** on a trailing end of the first end cap **16**. (**Figure 2; Specification, p. 11, lines 8-9**).

Dependent **claim 35**, which depends from dependent **claim 24**, further comprises the filter member **20** sealed by a removable second sealing cap **24** on a leading end of the filter member **20**. (**Figure 2; Specification, p. 11, lines 8-9**). Dependent **claim 36**, which depends from independent **claim 23**, further comprises bone marrow aspirate **A** in the tube **10**, the bone marrow aspirate **A** having been introduced into the tube **10** through the first end **12** of the tube **10**, and air having been expelled through the filter **50** of the filter member **20** to facilitate introduction of the bone marrow aspirate **A** into the tube **10**. (**Figures 6B and 7; Specification, p. 12, line 25-p. 13, line 2**).

Dependent **claims 37-39** depend from dependent **claim 36**. Dependent **claim 37** further specifies that the bone marrow aspirate **A** has been allowed to coagulate in the tube **10** while in contact with the bone graft material **M**. (**Specification, p. 13, lines 16-20**). Dependent **claim 38** specifies that the bone graft material **M** is substantially saturated with the bone marrow aspirate **A**. (**Specification, p. 10, lines 24-26, p. 16, lines 17-18**). Dependent **claim 39** further comprises coupling a second sealing cap **24** to the filter member **20** to thereby provide a relatively air tight environment after air has been expelled from the tube **10**. (**Figure 2; Specification, p. 11, lines 8-9**).

Dependent **claims 40-44** present a series of nested claims. Dependent **claim 40**, which depends from dependent **claim 36**, further specifies that the bone graft material **M** comprises tri-calcium phosphate. (**Specification, p. 10, lines 14-16**). Dependent **claim 41**, which depends in series from dependent **claims 23, 36**, and **40**, further comprises a first washer **38** disposed between the first end cap **16** and the first end **12** of the tube **10**. (**Figure 2; Specification, p. 11, lines 23-26**). Dependent **claim 42**, which depends in series from **claims 23**, **36**, **40** and **41**, further comprises a second washer **40** disposed between the second end cap **18** and the second end **14** of the tube **10**. (**Figure 2; Specification, p. 11, lines 23-26**). Dependent **claim 43**, which depends in series from **claims 23**, **36**, and **40-42**, specifies that the trailing end of the first end cap **16** that is configured for attachment to a bone marrow aspirate delivery member **100** is further specifically configured for attachment to a syringe **100**. (**Figure 6B; Specification, p. 11, line 31-p. 12, line 2**). Dependent **claim 44**, which depends in series from **claims 23**, **36**, and **40-43**, further comprises coupling a second sealing cap **24** to the filter member **20** to thereby provide a relatively air tight environment after air has been expelled from the tube **10**. (**Figure 2; Specification, p. 11, lines 8-9, p. 13, lines 10-15**).

6. *Grounds of Rejection to be Reviewed on Appeal*

Claims 23 - 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Muschler (U.S. Patent 6,723,131) in view of Wironen et al. (U.S. 2003/0180262 Al).

7. *Argument*

Each argument against the prior art rejection of record is set forth below.

Claims 23 - 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Muschler (U.S. Patent 6,723,131) in view of Wironen et al. (U.S. 2003/0180262 Al). Applicant is of the view that a prima facie showing of obviousness has not been established.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the references or to combine the reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim elements. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ.2d 1438 (Fed. Cir. 1991).

In this case, the Examiner admits that the cited references do not teach all of the claim elements, attempts to rely on an admission by applicant to supply the missing elements, and fails to identify a suggestion or motivation in the cited references for arriving at the claimed apparatus, particularly since the proposed combination would destroy the function of the Muschler reference. Under the circumstances, it is respectfully suggested that a *prima facie* showing of obviousness has not been established.

The Examiner takes the position that Muschler teaches a bone graft material, apparatus and method for making a bone graft material having various characteristics of the claimed invention. The Examiner admits that Muschler does not teach methods or an apparatus in which air is expelled. The Examiner takes the position that Wironen teaches methods and apparatuses for making bone graft composites in which air is expelled from the tube containing the bone material, citing Wironen ¶ 0022, 0034, 0043, 0045. According to the Examiner, Wironen teaches that it is typically desirable to remove air from the paste components before, during or after reconstitution is conducted, citing Wironen ¶ 0045. The Examiner concludes that at the time of the claimed invention, one of ordinary skill in the art would have been motivated by Wironen to ensure that air is expelled since the reference teaches the desirability to do so. Moreover, according to the Examiner, it would have been obvious to one of ordinary skill in the art at the time of the invention to remove any air from the apparatus of Muschler, as guided by Wironen.

Importantly, the Examiner admits that the cited references do not specifically identify each of the claimed limitations. Without identifying which limitations are missing from the cited references, the Examiner nonetheless attempts to overcome this deficiency in the obviousness showing by relying on applicant's admission that each of the inventions are obvious over each other within the meaning of 35 USC § 103. As will be discussed below, applicant's admission was made in the context of a five-way restriction requirement over five sets of claims that were very similar to one another, and which are no longer pending. The Examiner concludes that because of applicant's admission, it would have been obvious to one of ordinary skill in the art to make, use and practice the claimed inventions as disclosed by Muschler and (allegedly) admitted by applicant. Notably, as discussed in detail at pp. 11-16, the Examiner did not explain how applicant's admission would somehow render the pending claims obvious over the cited art.

By focusing on applicant's admission, the Patent Office appears to have lost site of the determinative issue. The question is not whether the present claims are obvious over some type of yet-to-be-explained application of applicant's original sets of claims to the teachings of the cited references. The question is whether applicant's present claims are obvious over the prior art, particularly in view of the fact that the proposed combination would destroy the function of the cited references, and the Examiner's admission that the cited references do not teach all elements of the claimed invention. The central question is whether it would have been obvious to a person of ordinary skill in the art to combine the teachings of Muschler and Wironen to arrive at the claimed invention. Under § 103(a) and applicable case law, it is the Examiner's burden to demonstrate that the cited references provide a suggestion, motivation or teaching to arrive at the claimed invention. For the reasons discussed below, applicant respectfully suggests that the Examiner has not met this burden.

As the Examiner has admitted, the cited reference does not specifically identify each of the claimed limitations. There is a gap in the teachings of the cited Muschler and Wironen references, and applicant respectfully suggests that when the cited references are carefully studied, they do not provide the required suggestion or teaching necessary to fill the gap. Indeed, the cited references cannot be combined without destroying the stated objective of the Muschler reference.

Nothing in Muschler suggests the need to remove air from the Muschler enriched bone graft, much less the need to remove air while preventing passage of bone marrow aspirate. Muschler specifically teaches away from this aspect of the claimed invention in at least two fundamental ways: (1) Muschler describes a screen or membrane that allows bone marrow aspirate to pass through Muschler's matrix material; and (2) the objective of Muschler is to provide a composite bone marrow graft material having an enriched population of progenitor cells.

With regard to Muschler's screen or membrane, Muschler states: "Optionally, endcaps 14 can be provided with a screen or membrane 15 (see FIG. 8) ***effective to allow aspirate 20 to pass therethrough***, while retaining particles of matrix 10." (Muschler, Col. 7, lines 15-17; emphasis added). The only other place where Muschler mentions the membrane 15 is at Col. 10, lines 47-49, where Muschler states simply: "Optionally, the kit is provided with a porous biocompatible implanted substrate for use as a bone graft matrix, and porous membranes 15 to retain a matrix within the matrix container." Thus, Muschler describes the membrane 15 as being configured to ***allow bone marrow aspirate to pass therethrough***, and ***nowhere does Muschler suggest the need to configure the membrane to prevent passage of bone marrow aspirate while allowing passage of air***.

In direct contradiction to Muschler, applicant claims an apparatus that allows for removal of air while retaining bone marrow aspirate in the tube. Removing air while retaining bone marrow aspirate in the container runs counter to the very purpose of Muschler, which is to produce a "composite bone marrow graft material [having] an enriched population of progenitor cells." (Muscler, Col. 2, lines 40-41). Key distinctions between Muschler and the claimed invention are highlighted at Muschler Col. 7, lines 39-Col. 8, line 11. Muschler specifically describes a process in which the bone marrow aspirate passes entirely through the matrix 10 in order to create the enriched graft material: "First loading syringe 28 is then plunged, delivering aspirate 20 into column 12 where ***aspirate 20*** flows through or contacts matrix 10 ***prior to being collected at the opposite end of column 12 in second loading syringe 29***." (Col. 7, lines 39-42; emphasis added). Muschler describes how the process of flowing the bone marrow aspirate through the matrix 10 results in an enriched graft: "Progenitor cells advantageously and selectively adhere to the surface of matrix 10, and hence are retained within the matrix while excesses of other cells, such as blood cells and other marrow-derived nucleated cells, flow relatively freely through the matrix and are collected in second loading syringe 29." (Col. 7, lines 48-53). According to Muschler, after using the Muschler process of flowing the aspirate through the matrix, the resulting graft contains between a 2 to 8 fold increase in the ratio of progenitor cells compared to natural bone marrow aspirate. (Col. 7, line 61-Col. 8, line 3).

In distinct contrast with Muschler, applicant's claims are directed to a tube that allows for expelling air from the tube while ***retaining*** the bone marrow aspirate in the tube. Because all of the bone marrow aspirate is retained in the tube, the ratio of progenitor cells to natural bone marrow aspirate does not change. Thus, the use of applicant's claimed tube will not result in a matrix having an increased ratio of progenitor cells. Furthermore, if Muschler were modified to include a filter that allowed air to pass through while retaining bone marrow aspirate, the stated function of Muschler (to increase the ratio of progenitor cells) would be destroyed.

In applicant's specification, applicant discussed the foregoing features of Muschler with reference to Muschler's U.S. Patents 5,824,084 and 6,049,026[1] as follows:

> The [Muschler] bone graft is prepared by providing a bone marrow aspirate suspension and passing the bone marrow aspirate suspension through a porous, biocompatible, implantable substrate resulting in a composite bone graft having an enriched population of connective tissue progenitor cells that collects in an effluent collector separate from the mixing chamber (i.e., container 14).

(Applicant's specification, p. 6, line 29-p. 7, line 2). After explaining the foregoing features of Muschler, applicant noted that applicant's invention "offers flexibility by allowing the composite to be mixed (i.e infused) in the operating room . . . using the patient's own healing potential in the form of bone marrow aspirate, blood, or platelet concentrate." (Applicant's specification, p. 7, lines 5-7). As a key feature of applicant's apparatus, applicant noted: "The filter on the second end of the tube allows air to be expelled from the tube as it is filled with the bone marrow aspirate. However, the filter should be sufficiently dense to prevent leakage of the bone marrow aspirate." (Applicant's specification, p. 7, lines 21-23). Thus, directly counter to the teaching of Muschler, applicant teaches providing a filter on the second end that does not allow bone marrow aspirate to pass through. The teaching to provide such a filter and the resulting function is provided in applicant's specification, not in the cited prior art.

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[1] When applicant filed the specification, the cited Muschler reference, U.S. Patent 6,723,131, had not yet issued.

The claimed apparatus, which has been selling successfully, allows a surgeon to prepare a useful bone marrow aspirate derived bone graft material quickly and efficiently in the operating room. In actual practice, applicant has found that a bone marrow aspirate impermeable filter member on the second or leading end of the tube is an important feature of the apparatus because it enables the tube to be filled with as much bone marrow aspirate as possible, which in turn exposes the bone graft material to as much bone marrow aspirate as possible. Without a filter, the bone marrow aspirate simply flows across the bone graft material, and consequently the bone graft material can only absorb bone marrow aspirate components that flow past the bone graft material. Fluid pressure created in the tube during expulsion of air through the filter creates back flow, which further circulates bone marrow aspirate within the bone graft material. (See Applicant's Figure 7). With the filter on the leading end of the tube, all of the bone marrow aspirate is retained and, after a selected period of coagulation, a more uniformly shaped piece of composite bone graft material is obtained. The foregoing features are particularly useful in the operating room, because they enable formation of a composite bone marrow aspirate bone graft material using relatively simple instruments and methods, and within a time frame suitable to surgical procedures. As discussed in applicant's specification, the claimed apparatus enables the foregoing functions.

In attempting to combine the teachings of Muschler and Wironen to support a showing of obviousness, the Examiner notes that Wironen teaches methods and apparatuses for making bone graft composites in which the air is expelled from the tube containing the bone material, citing ¶¶ 0022, 0034, 0043, and 0045 of Wironen. The Examiner takes the position that Wironen teaches that it is typically desirable to remove air from the paste components before, during or after reconstitution is conducted, citing Wironen ¶0045. The Examiner concludes that at the time of the claimed invention, one of ordinary skill in the art would have been motivated by Wironen to ensure that air is expelled since the reference clearly teaches the desirability to do so, and further, that it would have been obvious to one of ordinary skill in the art to remove any air from the apparatus of Muschler, as guided by Wironen.

In contrast with Muschler, Wironen makes no mention of the use of a bone marrow aspirate. Consequently, Wironen makes no suggestion of the desirability of retaining bone marrow aspirate while expelling air. Rather, Wironen is concerned with the problem of preserving and storing bone pastes. As explained in ¶0003 of Wironen, "While current methods of utilizing bone paste have shown promise, there is a constant need for devising new, cost-effective techniques of storing and preserving bone paste and other biomedical substances, which, in turn, will increase their usefulness and adaptability to medical applications." The preservation and storage of bone pastes is an entirely different function than that of the claimed apparatus. As discussed above, the claimed apparatus allows a surgeon to efficiently prepare a useful bone marrow aspirate derived bone graft material in the operating room for use *during* the operation. Preserving the bone graft is not the object of the claimed invention, and it is unclear how doing so would provide a benefit, since the bone marrow aspirate naturally solidifies (coagulates) around the bone graft material and becomes more firm over time. (Specification, p. 13, lines 16-20).

In the few places where Wironen discusses the expulsion of air from a syringe, there is no suggestion that expulsion of air can be used to improve the process of forming a composite bone graft material from bone marrow aspirate. Of the four places where Wironen mentions "air," only one place describes expelling air from the syringe. ¶0022 is merely a brief description of drawing Figure 10. ¶0034 is concerned not with expelling air but rather with minimizing "dead" space between the two syringes, thereby alleviating unwanted air bubbles. Thus, ¶0034 is concerned with minimizing air bubbles rather than with expelling air. ¶0043 describes a relatively complicated method of removing air from a bone paste using three syringes joined by a three-way stop valve. ¶0045 provides a detailed description of Figure 10, which depicts a syringe in which removal of air is facilitated by providing an aperture in the plunger of the syringe. In

Wironen Figure 10, the plunger 1000 has an aperture 1010 at its end 1020 in contact with paste components, wherein the aperture communicates with the other end of the plunger 1030 through a channel 1040 defined within the plunger 1000. Preferably, to prevent escape of paste components or reconstitution fluid, the aperture is covered with an air-permeable membrane or filled with an air-permeable plug. As the plunger is pushed against the contents of the syringe, the pressure caused thereby acts to push the air contained in the contents through the aperture and expelled out of the syringe. (See Wironen, ¶0045). The structure of Wironen Figure 10 differs significantly from that of the claimed invention. Notably absent from Wironen is any suggestion or teaching of the desirability of retaining bone marrow aspirate while expelling air.

Considering all of the foregoing, it is respectfully submitted that a prima facie case of obvious has not been established. The Examiner admits that the cited references do not teach all of the claim limitations (but without identifying which limitations are missing from the cited references). The cited references lack the required suggestion or teaching necessary to arrive at the claimed invention. Combining the references in the manner suggested by the Examiner would destroy the stated function of Muschler. Applicant's specification is being used to supply the required suggestion to combine, resulting in hindsight reconstruction of the claimed invention.

Having addressed the substantive grounds of the obviousness showing, applicant now turns to the Examiner's reliance on applicant's admission as a basis for supplying elements that are admittedly missing from the cited references.

Applicant has several objections to the Examiner's reliance on applicant's admission. First, applicant respectfully submits that applicant's admission, which was made in response to the five-way restriction requirement, is being taken out of context and is now moot. Second, in relying on applicant's admission, the Examiner appears to be losing sight of the determinative issue of obviousness. Third, the Examiner has not explained how applicant's admission renders the claimed invention obvious over the cited art, and consequently has not provided applicant with an opportunity to adequately respond to the basis of the rejection.

Applicant's admission concerning obviousness was made in response to a five-way restriction requirement involving five sets of claims that were very similar to one another.

Because the five claim sets were very similar, applicant was of the view that the Patent Office had not met its burden of establishing that the application claimed five independent and distinct inventions. Rather than traverse the restriction requirement, applicant elected to admit that the claims were obvious over each other so that all five sets of similar claims could be examined in the same application. In particular, applicant stated:

> In view of the similarity in the structure and elements of the claims and *applicant's concern that a showing of distinctiveness has not been made*, applicant admits that the claimed inventions would have been obvious over each other within the meaning of 35 U.S.C. 103. Therefore restriction between Inventions I, II, III, IV and V should not be required. See MPEP § 803; *In re Lee*, 199 USPQ 108 (Comm'r Pat. 1978).
>
> Based on the prior art, it appears to applicant that claims of the type presented in the present application are routinely classified in Class 623, Subclass 16 or 23 (see e.g. U.S. 5,824,084; U.S. 6,049,026). It is not clear to applicant why the claims of the present application would be classified in either Class 424 or 435, as suggested by the Examiner in the foregoing claim groupings. Applicant is of the view that the inventions as claimed have not achieved a separate classification, that the field of search is the same, that search and examination of all of the claims can be made without serious burden, and that the Patent Office has not met its burden of demonstrating distinctiveness between the five sets of claims. It also appears to applicant that February 14, 2006 restriction requirement did not attempt to make a showing of distinctiveness between the following inventions: I and III; I and V; and IV and V. However, as noted above, restriction should not be required in view of applicant's admission.

(Applicant's September 1, 2006 Response, pp. 5-6; emphasis added).

Although applicant later decided to cancel the original five sets of similar claims and pursue a single set of claims, the Examiner maintains that applicant's admission renders the current claims obvious by supplying elements that are missing from the cited references. The Examiner further concludes that the statement cannot be expunged from the record. Applicant does not seek to "expunge" the admission from the record, but rather is of the view that the statement is being taken out of the context of the procedural issue to which the statement was directed, and that the admission is moot now that applicant has elected to pursue a single set of claims. When applicant made the admission, applicant was attempting to find an efficient way to deal with what appeared to be an extreme five-way restriction requirement. In making the admission, applicant specifically noted its concern that a showing of distinctiveness had not been made. (See pp. 5-6 of applicant's response, supra). This is clearly not a situation where applicant was attempting to short-cut restriction practice and put an undue burden on the Examiner, but rather one where applicant genuinely did not believe that the requisite showing of distinctiveness had been made, and decided that the most efficient way to deal with the issue was to make the standard procedural admission. Applicant's claims should be examined on the merits relative to the prior art, not summarily rejected based on applicant's attempt to resolve a genuine disagreement over a restriction requirement by using a standard and longstanding procedural practice.

The closest analogous case appears to be *Quad Environmental Technologies Corp. v. Union Sanitary District*, 946 F.2d 870, 20 USPQ2d 1392, 1394 (Fed. Cir. 1991), in which the Federal Circuit held that a terminal disclaimer "is not an admission of obviousness of the later filed claimed invention in light of the earlier filed disclosure. . . . In legal principle, the filing of a terminal disclaimer simply serves the statutory function of removing the rejection of double patenting, and raises neither presumption nor estoppel on the merits of the rejection." *Id.* at 1394. Like a terminal disclaimer filed in response to an obviousness type double patenting rejection, applicant's statement was directed to the procedural question of whether a five-way restriction was proper, not to the substantive merits of a pending rejection. At the time of the admission, applicant did not know what prior art the Examiner would eventually cite, and applicant therefore certainly did not admit that the claims were obvious over the cited references. Applicant also did not know how the claims would be amended in the future. Needless to say, applicant did not admit that the current set of claims are obvious over the claims that were pending at the time of the restriction requirement.

However, even if applicant's statement is not considered moot under the circumstances presented, which applicant obviously disputes, the Examiner has made no effort to explain how the admission renders the claimed invention obvious. The Examiner's first reliance on applicant's admission appeared in the first office action on the merits, where the Examiner stated simply:

> The reference does not specifically identify each of the claimed limitations. However, in the reply filed on March 14, 2006, applicant has clearly admitted on record that each of the instant inventions are obvious over each other within the meaning of 35 USC 103. Thus, at the time of the claimed invention, it

> would have been obvious to one of ordinary skill in the art to make, use and practice the claimed inventions as disclosed by Muschler. Wironen, and admitted by applicant.

(June 1, 2006 Non-Final Office Action, p. 9). The Examiner repeated the same language at page 12 of the June 1, 2006 office action.

When applicant responded to the June 1, 2006 office action, applicant elected to pursue a single set of claims, cancelled the original five sets of claims, and stated: "Applicant withdraws its prior statement that the claimed inventions would have been obvious over each other within the meaning of 35 U.S.C. 103."

In the November 30, 2006 final office action, the Examiner took the position that applicant's previous statement could not be "expunged" from the record. Although new claims were pending in the case, the Examiner continued to rely on applicant's response to the restriction requirement, repeating the very same language that had been used in the June 1, 2006 office action:

> The reference does not specifically identify each of the claimed limitations. However, in the reply filed on March 14, 2006, applicant has clearly admitted on record that each of the instant inventions are obvious over each other within the meaning of 35 USC 103. Thus, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to make, use and practice the claimed inventions as disclosed by Muschler and admitted by applicant.

(Nov. 30, 2006 Final Office Action, p. 5). As in the previous action, no further reasons were provided.

In responding to the final office action, applicant took the position that the foregoing statement merely sets forth a conclusion, is not sufficient to establish a prima facie showing of obviousness, and does not provide applicant with enough information to respond to the Examiner's contention that applicant's admission renders the claims obvious. Applicant requested clarification and withdrawal of final rejection status so that applicant could undertake a meaningful analysis of the Examiner's position. In reply, in the February 13, 2007 Advisory Action, the Examiner provided the following additional statement:

> [The request for reconsideration] does NOT place the application in condition for allowance because: as stated in the previous office actions, applicant

> has admitted on the record that the inventions are obvious over each other. Thus, a reference that teaches the bone materials and methods of the present invention would further render apparatuses and methods obvious under USC 103 (a). Moreover, since the art teaches materials and methods as claimed by applicant, other limitations not specifically disclosed are rendered obvious over each other under the meaning of USC 103(a), as clearly admitted by applicant.

(February 13, 2007 Advisory Action, p. 2).

It is respectfully suggested that the foregoing statements by the Examiner merely set forth a conclusion, provide no explanation for the basis of the conclusion, are not sufficient to establish a prima facie showing of obviousness, and do not provide applicant with enough information to adequately respond to the Examiner's position. As MPEP ¶ 2142 makes clear, as part of the burden of making a prima facie showing, the Examiner must present reasoning supporting the obviousness rejection. When the motivation to combine the teachings of the references is not immediately apparent, it is the duty of the examiner to explain why the combination of the teachings is proper. *Ex parte Skinner*, 2 USPQ2d 1788 (Bd. Pat. App. & Inter. 1986). As the Federal Circuit stated in *In re Oetiker*, 977 F.2d 1443, 24 USPQ.2d 1443, 1447 (Fed. Cir. 1992):

> [T]he examiner cannot sit mum, leaving the applicant to shoot arrows in the dark hoping to somehow hit a secret objection harbored by the examiner. The "prima facie" case notion . . . seemingly was intended to leave no doubt among examiners that they must state clearly and specifically any objections (the prima facie case) to patentability, and give the applicant fair opportunity to meet those objections with evidence and argument.

In the present case, applicant respectfully suggests that it has not been given a sufficient explanation. Under the current record, applicant simply does not have enough information to attempt to counter the Examiner's position that applicant's admission renders the claims obvious. As noted above, applicant requested clarification and withdrawal of final rejection status so that applicant could undertake a meaningful analysis of the Examiner's position. Applicant's request was not acted upon. If additional grounds for the Examiner's position are presented for the first time on appeal, then it is respectfully suggested that this application is not ripe for appeal and should be remanded, unless the Board finds the issue moot.

For the reasons set forth above, applicant respectfully requests that the Board overturn the rejections of record.

8. *Claims Appendix*

An appendix containing a copy of the claims involved in the appeal is attached below.

9. *Evidence Appendix*

None.

10. *Related Proceedings Appendix*

None.

CONCLUSION

In view of the foregoing arguments, Appellant respectfully submits that Claims 23-44 are patentable over the cited references. A decision from the Board of Patent Appeals and Interferences reversing the final rejection of the pending claims is therefore earnestly solicited.

Respectfully submitted,

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CLAIMS APPENDIX

1-22. (Cancelled)

23. (Previously presented) An apparatus for preparing a bone graft composite comprising a bone graft material and a bone marrow aspirate, the apparatus comprising:

a tube having a first open end and a second open end;

a first end cap removably coupled to said first open end, said first end cap having a passage therethrough to allow fluid communication between a bone marrow aspirate delivery member and said tube, a trailing end of said first end cap configured for selective attachment to a bone marrow aspirate delivery member;

a second end cap removably coupled to said second end, said second end cap having a passage therethrough to allow fluid communication between said tube and a filter, a leading end of said second end cap configured for selective attachment of a filter;

a filter member removably coupled to said leading end of said second end cap;

a filter in said filter member, said filter configured to prevent bone marrow aspirate from passing therethrough while permitting air to pass therethrough, said filter in fluid communication with said tube via said passage of said second end cap; and

a bone graft material in the tube.

24 (Previously presented) The apparatus of claim 23, wherein said bone graft material is selected from the group consisting of calcium sulfate, calcium phosphate, tri-calcium phosphate, hydroxyapatite, coral hydroxyapatite, demineralized bone matrix, and mineralized bone matrix.

25. (Previously presented) The apparatus of claim 23, wherein said bone graft material comprises tri-calcium phosphate.

26. (Previously presented) The apparatus of claim 23, wherein said bone graft material is porous to bone marrow aspirate.

27. (Previously presented) The apparatus of claim 23, wherein said bone graft material comprises a plurality of small pieces of bone graft material.

28. (Previously presented) The apparatus of claim 23, further comprising said first end cap sealed by a removable first sealing cap on a trailing end of said first end cap.

29. (Previously presented) The apparatus of claim 28, further comprising said filter member sealed by a removable second sealing cap on a leading end of said filter member.

30. (Previously presented) The apparatus of claim 23, further comprising a first washer disposed between said first end cap and said first end of said tube.

31. (Previously presented) The apparatus of claim 30, further comprising a second washer disposed between said second end cap and said second end of said tube.

32. (Previously presented) The apparatus of claim 25, wherein said bone graft material comprises a plurality of small pieces of bone graft material.

33. (Previously presented) The apparatus of claim 32, further comprising a first washer disposed between said first end cap and said first end of said tube, and a second washer disposed between said second end cap and said second end of said tube.

34. (Previously presented) The apparatus of claim 33, further comprising said first end cap sealed by a removable first sealing cap on a trailing end of said first end cap.

35. (Previously presented) The apparatus of claim 24, further comprising said filter member sealed by a removable second sealing cap on a leading end of said filter member.

36. (Previously presented) The apparatus of claim 23, further comprising bone marrow aspirate in said tube, said bone marrow aspirate having been introduced into said tube through said first end of said tube, and air having been expelled through said filter of said filter member to facilitate introduction of said bone marrow aspirate into said tube.

37. (Previously presented) The apparatus of claim 36, wherein said bone marrow aspirate has been allowed to coagulate in said tube while in contact with said bone graft material.

38. (Previously presented) The apparatus of claim 36, wherein said bone graft material is substantially saturated with said bone marrow aspirate.

39. (Previously presented) The apparatus of claim 36, further comprising coupling a second sealing cap to said filter member to thereby provide a relatively air tight environment after air has been expelled from the tube.

40. (Previously presented) The apparatus of claim 36, wherein said bone graft material comprises tri-calcium phosphate.

41. (Previously presented) The apparatus of claim 40, further comprising a first washer disposed between said first end cap and said first end of said tube.

42. (Previously presented) The apparatus of claim 41, further comprising a second washer disposed between said second end cap and said second end of said tube.

43. (Previously presented) The apparatus of claim 42, wherein said trailing end of said first end cap configured for attachment to a bone marrow aspirate delivery member is configured for attachment to a syringe.

44. (Previously presented) The apparatus of claim 43, further comprising coupling a second sealing cap to said filter member to thereby provide a relatively air tight environment after air has been expelled from the tube.

EVIDENCE APPENDIX

None.

RELATED PROCEEDINGS APPENDIX

None.